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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,811

09/14/2006

Chikara Ohyama

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7590

04/16/2010

SUGHRUE MION, PLLC

2100 PENNSYLVANIA AVENUE, N.W.

SUITE 800

WASHINGTON, DC 20037

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

04/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com

PPROCESSING@SUGHRUE.COM

USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,811	<b>Applicant(s)</b> OHYAMA ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15-23 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendments and Arguments***

1. Claims 1-7 and 15-23 are pending.

Claims 11-13, drawn to non-elected inventions and are not examined on the merits.

Claims 8-10 have been cancelled.

Claims 1, 4, 5 and 7 have been amended.

Claims 15-23 have been added.

Claims 1-7 and 15-23 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' cancellation of claim 9 in the amendment submitted January 25, 2010. Claims 8-10 have been cancelled.

***Claim Rejections - 35 USC § 102***

5. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Machida et al. (Cancer Research 61: 2226-2231, March 1, 2001) is withdrawn in light of claim amendments and Applicants' arguments, see Remarks submitted January 25, 2010, page 7, 4<sup>th</sup> paragraph. Claims 8-10 have been cancelled.

6. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Shimodaira et al. (Cancer Research 57: 5201-5206, December 1, 1997/ IDS reference submitted September 19, 2005) is withdrawn in light of claim amendments and Applicants' arguments, see Remarks submitted January 25, 2010, Rejections...Shimodaira section beginning on page 7. Claims 8-10 have been cancelled.

7. The rejection of claims 1-7 under 35 U.S.C. 102(a) as being anticipated by Ohyama et al. (Glycobiology 13(11): 864, November 2003/ IDS reference submitted May 14, 2007) is withdrawn in light of claim amendments and Applicants' arguments, see Remarks submitted January 25, 2010, Rejections...Ohyama section beginning on page 8. The date of Ohyama falls after Applicants' effective filing date. Claims 8-10 have been cancelled.

***New Grounds and Maintained Rejections***

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The rejection of claims 1-6 and new claims 14-23 under 35 U.S.C. 102(b) as being anticipated by Fukuda et al./U.S. Patent number 6,136,580 (issued October 24, 2000) is maintained and made. Claims 8-10 have been cancelled.

Applicants' assert even though Fukuda "...describe[s] immunological detection of C2GnT-M...and does not disclose a method of detecting the prognosis of cancer in which elevated levels of C2GnT indicate an increased risk of cancer recurrence", see Remarks submitted January 25, 2010, page 7, 1st full paragraph. Applicants' conclude arguments noting Fukuda does not teach each and every element in the pending claims, see Remarks, page 7. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants reads on two active steps, detecting core 2  $\beta$ 1,6-N-acetylglucosaminyltransferase in a sample and analyzing the sample. Fukuda reads on those two steps, see column 14, line 62- column 15, line 66. The wherein clauses set forth in the claims merely states the results of the two

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limitations or steps in the claim and adds nothing to the patentability or substance of the claim, hence it not given weight. It simply expresses the intended result of the positively recited process steps. The wherein clauses read on a characterization of meeting the two active steps and do not impart novelty. Consequently, Fukuda anticipates the claims and the rejection is maintained and made.

Fukuda discloses a method of detecting mammalian polypeptide core 2, core 4 and I branching 1,6-*N*-acetylglucosaminyltransferase (C2GnT-M) and core 2 1,6-*N*-acetylglucosaminyltransferase (C2GnT-L) in various human tissues and cancer cell lines using immunological procedures, see column 15, lines 31-42.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the

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advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday on 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
06 April 2010

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643